

AMENDMENTS TO THE DRAWINGS:

The attached sheet 3/3 of drawings includes changes to Figure 5. This sheet, which includes both Figures 5 and 6, replaces the original sheet 3/3 including Figures 5 and 6. In Figure 5, the "electrode spacing of ≤ 10 " is amended as a "electrode pair spacing $\leq 1 \mu\text{m}$ " as disclosed at page 5, line 1 of the specification.

Attachment: Replacement Sheet

REMARKS

This application is amended in a manner to place it in condition for allowance at the time of the next Official Action.

Status of the Claims

Claims 1-20 are amended as to form and to clarify the claimed invention.

Claim 1 is amended substantively in a manner consistent with the paragraph bridging pages 4 and 5 of the specification and Figure 5.

Claim 3 is amended substantively in a manner consistent with specification page 5, lines 10-13 in light of specification page 4, line 21 to page 5, line 9 and Figures 1, 4 and 5.

Claim 9 is amended substantively in a manner consistent with page 5, lines 5-6 in light of page 5, lines 3-4.

It is believed that no new matter has been added to these amended claims.

Claims 1-20 remain in this application.

Claim Objections

Claims 2 and 8 were objected to because of informalities. These claims have been amended as suggested in the Official Action, and withdrawal of the objection is respectfully requested.

Drawings

The Drawings were objected to for several informalities.

Figure 1 and 4 were objected for including the character "10" without making reference to it in the discussion of these Figures. The Official Action recognized, however that Figure 4 did refer to "10" as the sensor chip.

It is respectfully submitted that it should be apparent that "10" in Figure 1 refers to the "sensor chip", e.g., as feature "3" refers to the gold electrodes of "the sensor chip".

Moreover, it should also be apparent based on the context of "sensor chip" and "biochip" that these terms are interchangeable, for example in the description of the biosensor beginning at line 25 on page 4 and ending on page 5.

However, for clarity, the discussions of Figure 1 in the present specification have been amended to disclose "sensor chip, or biochip" at page 4-line 4, page 5-line 7, page 5-line 23, and at page 6, line 16, where specific reference is made to "sensor chip 10, or biochip of Fig. 1".

Figure 5 was objected to for labeling the electrode spacing as " ≤ 10 " instead of " $\leq 1 \mu\text{m}$ " as disclosed in the specification. Accordingly, Figure 5 has been amended to refer to "electrode pair spacing $\leq 1 \mu\text{m}$ " as disclosed at page 5, line 1 of the specification. Additionally, the paragraph beginning at page 4, line 21, has been rewritten to describe that electrodes (13)

are comb-like electrode fingers of the interdigital structures, and that the spacing between the electrode pairs of a maximum of 1.0 μm .

It is believed that no new matter has been added to either the drawings or the specification.

Therefore, in light of the amendments to the specification and Figure 5, withdrawal of the drawings objection is respectfully requested.

Claim Rejections-35 USC §112

Claims 1-20 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite.

Specifically, claims 1, 3, 8, 9, 12 and 13 were rejected for reciting unclear and vague terms. Accordingly, these claims are amended to clarify the claimed invention in a manner consistent with the specification.

For example, claim 1 is amended in a manner consistent with the paragraph bridging pages 4 and 5 of the specification and Figure 5. Claim 3 is also amended in a manner consistent with specification page 5, lines 10-13 in light of specification page 4, line 21 to page 5, line 9 and Figures 1, 4 and 5. Claim 9 is amended in a manner consistent with page 5, lines 5-6 in light of page 5, lines 3-4. Claims 12 and 13 are amended in a manner consistent with U.S. practice.

Therefore, withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §103

Claims 1, 4-9 and 18-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over WOHLSTADTER, et al. U.S. Patent No. 6,673,533 (WOHLSTADTER) in view of EL SHAMI et al. U.S. 4,778,751 (EL SHAMI) and NIWA et al. (NIWA). This rejection is respectfully traversed for the reasons below.

WOHLSTADTER discloses many ways to provide a biosensor. However, there is no single biosensor disclosed with all of the features as recited in claim 1.

For example in Figure 19 of WOHLSTADTER, the interdigital electrode is identical to the counter electrode and working electrode. In the claimed invention, however, there is a counter-electrode in addition to the interdigital electrode on the same substrate.

Another difference between the claimed invention and WOHLSTADTER, as acknowledged by the Official Action, is the spacing between the electrode pairs of the interdigital electrode.

Yet another difference is in the protein layer disclosed in WOHLSTADTER. WOHLSTADTER (column 8, Figure 49) discloses a first coat protein is on silica particles on a fibril mat electrode. The electrochemical and chemical behavior of this

protein coat is completely different than the protein coat on a flat gold surface according to the claimed invention, e.g., in claim 1. Moreover, e.g. in column 102, this protein coat is as a flat layer on a gold electrode on glass slides. The electrochemical behavior and preparation of such layers are different from the first protein layer on the claimed interdigital electrodes as claimed, and, thus, cannot compared to the claimed invention.

Another difference is that a second protein layer over the first layer with a capture antibody for the antigen, which is to be detected, is not described in WOHLSTADTER (e.g., in column 22). Instead, there are many binding reagents described without any preference, whereby antibodies are one possible reagent out of these many binding reagents. A protein layer with antibodies on top of a first protein layer is not described. In column 35, for example, WOHLSTADTER discloses a redox active species immobilized on a fibril mat, and in column 1 WOHLSTADTER discloses an enzyme linked to immunoassay. However, there is no biosensor described where an antigen is coupled to the capture antibody and by means of an enzyme-marked detection anti-body also coupled to the antigen, redox-reactive molecules are enzymatically released on a sensor surface.

Neither EL SHAMI nor NIWA is able to remedy the shortcomings of WOHLSTADTER for reference purposes.

EL SHAMI (column 2 to 3) discloses an immunometric assay for the detection of antigens with the help of immobilized antigens. However, EL SHAMI does not even set out to solve the same problem as WOHLSTADTER, and, thus, one of ordinary skill in the art would have had no reason to consider EL SHAMI to modify WOHLSTADTER. Moreover, even if one were to combine these documents, there is no description of an electrochemical detection or electrodes or protein layers systems or redox reactive molecules as described by the claimed invention, e.g., claim 1.

NIWA discloses an interdigitated array described usable for redox-cycling. However, there is no protein layer assembly or antigen/antibody detection described. With the exception of the interdigital electrodes on silicon, there are simply no features of the present claim 1 in NIWA. Moreover, there is commonality with either EL SHAMI or WOHLSTADTER.

Therefore, the proposed combination fails to render obvious independent claims 1, and the dependent claims, and withdrawal of the rejection is respectfully requested.

Claims 2-3 and 11-17 were rejected under 35 U.S.C. §103(a) as being unpatentable over WOHLSTADTER in view of EL SHAMI and NIWA, further in view of PETTIT et al. U.S. 6,548,644 (PETTIT). This rejection is respectfully traversed for the reasons below.

The combination of WOHLSTADTER, EL SHAMI and NIWA fail to teach or suggest the claimed invention for the reasons discussed above.

PETTIT was offered for teachings the proteins of the first protein layer, the binding partners of the first and second protein layers, the type of antigen, the signal detected, and the method of using the biosensor defined in claim 1, as well as the dependent claims.

However, regardless of the ability of PETTIT to teach that for which it is offered, PETTIT cannot remedy the deficiencies of the combination of WOHLSTADTER, EL SHAMI and NIWA discussed above. As discussed above, there would have been no reason to combine these documents, and even if there were, the combination would fail to teach various features of the biosensor of claim 1.

Therefore, the combination of WOHLSTADTER, EL SHAMI and NIWA with PETTIT fails to render obvious claims 2-3 and 11-17, and withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- ☒ - a Replacement Sheet for Figures 5 and 6 of the drawings